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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,874	11/03/2003	Arthur Kunz	040000-0375899	4900

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EXAMINER

FETTEROLF, BRANDON J

ART UNIT	PAPER NUMBER
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1642

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PatentDocketing@WCSR.COM

Office Action Summary	Application No. 10/699,874	Applicant(s) KUNZ ET AL.	
	Examiner BRANDON J. FETTEROLF	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 150-164, 167-174, 177-210, 213-222, 227-233, 236-251 and 257-268 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 150-153, 158-164, 167-174, 181-199, 204-210, 213-222, 227-233, 236-243 and 248-251 is/are allowed.
- 6) ☐ Claim(s) 154-157, 177-180, 200-203, 244-247 and 252-268 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/02/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION
Response to Amendment

The amendment filed on 8/07/2009 in response to the Non-Final Office Action (2/11/2009) is acknowledged and has been entered.

Claims 150-164, 167-174, 177-210, 213-222, 227-233, 236-251, 257-268 are currently pending and under consideration.

Claim Objections

Claims 154-157, 177-180, 200-203, 244-247 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the present case, it is unclear how the new claim limitations further limit the antibody as recited in the independent claims. In particular, the claims appear to broaden the scope of antibody claimed in the independent claim versus further limiting said sequence.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 200-203 and 244-247 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the instant case, the claims, as set forth above, attempt to further limit the human acceptor framework regions based on specific sequences. For example, dependent claim 200 recites “the a anti-CD22 antibody comprises a heavy chain framework residue selected from one or more positions 1, 28, 48, 72 and 97 (linear numbering occupied) by Glu, Arg, Ile, Ala and Thr , respectively, wherein the remainder of the heavy chain framework region is occupied by residues of

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the human acceptor framework of SEQ ID NO: 21 or 22. Thus, while the claims contemplate a heavy chain framework having the residues described above a particular positions and further the remainder occupied by SEQ ID NO: 21 or 22, the claims do not appear to limit what amino acid are encompassed by said antibody. In other words, the claims do not appear to describe the "structure" of the antibody, but instead leaves the antibody open to comprising an infinite number of residues but does not appear to describe how they all "fit" together.

Claims 257-268 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the instant case, the claims, as set forth above, attempt to further limit the antibody such that the antibody comprises a CDR-H2 sequence comprising an amino acid residue at a specific Kabat position. For example, claim 257 recites "wherein the antibody comprises a CDR-H2 sequence comprising an amino acid residue at Kabat position 55 other than asparagine." Thus, the claims appear to infer that there is a defined antibody structure in claim 196, since a specific Kabat position is being identified. However, all that is recited in claim 163 is an antibody having the 6 CDR's, but does not appear to limit the CDR's to a particular position within the antibody.

Claims 177-180 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 177, for example, recites the limitation "the heavy chain variable region" in first and 2nd line. However, there is insufficient antecedent basis for this limitation in the claim 173 from which claim 177 depends.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 200-203 and 244-247 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

In the instant case, the claims, as set forth above, attempt to further limit the human acceptor framework regions based on specific sequences. For example, dependent claim 200 recites “the a anti-CD22 antibody comprises a heavy chain framework residue selected from one or more positions 1, 28, 48, 72 and 97 (linear numbering occupied) by Glu, Arg, Lle, Ala and Thr , respectively, wherein the remainder of the heavy chain framework region is occupied by residues of the human acceptor framework of SEQ ID NO: 21 or 22. In the present case, the claimed limitation has no clear support in the specification and the claims as originally filed. Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to provide sufficient written support for the “limitation” indicated above. See MPEP 714.02 and 2163.06

It is noted that Applicants assert that support for this amendment can be found by the previously presented claim language, including the sequences of the donor variable regions set forth in SEQ ID NO: 7 and 8. Thus, while it appears that the described heavy chain framework regions occupied by specific residues, for example, appear to be found in SEQ ID NO: 8, the Examiner recognizes that the present claims do not appear to recite for example SEQ ID NO: 8, but instead encompass a genus of antibodies and the disclosure of one species having these specific residues does not appear to show possession of the genus now claimed.

Similarly, Claims 257-268 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

In the instant case, the claims, as set forth above, attempt to further limit the antibody such that the antibody comprises a CDR-H2 sequence comprising an amino acid residue at a specific Kabat position. For example, claim 257 recites "wherein the antibody comprises a CDR-H2

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sequence comprising an amino acid residue at Kabat position 55 other than asparagine." In the present case, the claimed limitation has no clear support in the specification and the claims as originally filed. Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to provide sufficient written support for the "limitation" indicated above. See MPEP 714.02 and 2163.06

It is noted that Applicants assert that support for this amendment can be found in Figure 4 and page 46, lines 1-22 of the application as originally filed. Thus, while it appears to describe specific CDR-H2 sequences, the Examiner recognizes that the present claims do not appear to recite the specific CDR-H2, but instead encompass a genus of antibodies and the disclosure of one species having these specific residues does not appear to show possession of the genus now claimed.

Additionally, Claims 154-157 and 177-180 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

In the instant case, the claims, as set forth above, attempt to further limit the human acceptor framework regions based on specific sequences. For example, dependent claim 154 recites "the heavy chain variable region is further modified to include one or more backmutations...." In the present case, the claimed limitation of "backmutations" has no clear support in the specification and the claims as originally filed. Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to provide sufficient written support for the "limitation" indicated above. See MPEP 714.02 and 2163.06

Claims 150-153, 158-164, 167-174, 181-199, 204-210, 213-222, 227-233, 236-243 and 248-251 are in condition for allowance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON J. FETTEROLF whose telephone number is (571)272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf
Primary Examiner
Art Unit 1642

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